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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/785,207 | 02/24/2004 | Shanta Modak | 070050.2534 | 8835 |
| 21003 | 7590 | 08/11/2009 | EXAMINER | |
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| NEW YORK, NY 10112-4498 | | | | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 08/11/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTS.COM

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/785,207 | Applicant(s) MODAK ET AL. | |
| | Examiner ALI SOROUGH | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-10,12,16,19,20,22 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-10,12,16,19,20,22 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07022009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/28/2009 has been entered.

Status of the Claims

Claims 6, 11, 13-15, 17, 18, 21, 23-32, and 34 are cancelled and claims 1 and 33 are amended. Therefore, claims 1-5, 7-10, 12, 16, 19, 20, 22, and 33 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1, 2, 3, 5, 7-10, 12, 16, 19, 20, and 22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-11, and 17 of copending Application No. 10/622272 **is maintained**.

Response to Applicant's Arguments

Applicant argues that since the overlapping claims have not yet been patented Applicants will agree to submit a terminal disclaimer at such necessary time. Therefore, the instant rejection of claims 1, 2, 3, 5, 7-10, 12, 13, 16, 19, 20, and 22 on the ground of nonstatutory obviousness-type double patenting is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 16, 19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Broh-Kahn et al. (US Patent 3257276, Published 06/21/1966) in view of Burnier et al. (US Patent 5736574, Published 04/07/1998) as evidenced by Page (US Patent 4870108, Published 09/26/1989).

Applicant Claims

Applicant claims a composition comprising alcohol, water, hydrogel, an emollient, octoxyglycerin and an antimicrobial.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Broh-Kahn et al. teach an oral analgesic hydroalcoholic gel comprising: 8.72% choline salicylate, 0.01% cetyldimethylbenzylammonium chloride (benzalkonium chloride), 2.75% methyl cellulose (gelling agent), 5% glycerine (emollient), 39.16% ethyl alcohol, 0.143% oil of anise, 0.057% menthol, 0.2% cyclohexylsulfamic acid, and ~44% water. (See title and column 5, Lines 13-25). The gelling agent concentration ranges from 0.1 to 4% depending on the desired viscosity of the finished gel. (See column 4, Lines 60-73).

Page teaches that glycerin is an emollient. (See column 2, Line 36).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Broh-Kahn et al. lacks a composition comprising octoxyglycerin. This deficiency is cured by the teachings of Burnier et al.

Burnier et al. teach combinatorial antimicrobial admixtures comprising at least one compound exhibiting antimicrobial activity and an antimicrobially synergistically effective amount of octoxyglycerin which are well suited for formulations in a wide variety of pharmaceutical and cosmetic compositions. (See abstract, Column 1, Lines 40-47, and Column 3, Lines 28-32). The antimicrobial action of this combination is advantageous since it is milder, while at the same time being at least as effective as that of the compounds of the prior art. (See column 1, Lines 48-50). The admixture preferably comprises 0.01 to 6% octoxyglycerin and 0.01 to 5% of the compound exhibiting antimicrobial activity. (See column 3, Lines 45-52).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the octoxyglycerin to the composition taught by Broh-Kahn et al., as suggested by Burnier et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Burnier et al. teach that the addition of octoxyglycerin to an antimicrobial such as

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benzalkonium chloride will result in the advantageous combination of a milder antimicrobial.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Broh-Kahn et al. (US Patent 3257276, Published 06/21/1966) in view of Burnier et al. (US Patent 5736574, Published 04/07/1998) further in view of Noda et al. (US Patent 4393076, Published 07/12/1983) as evidenced by Page (US Patent 4870108, Published 09/26/1989).

Applicant Claims

Applicant claims a composition comprising alcohol, water, hydroxyethylcellulose, an emollient, octoxyglycerin and an antimicrobial.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Brohn-Kahn et al. and Burnier et al. are discussed above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Broh-Kahn et al. lacks a composition comprising hydroxyethylcellulose. This deficiency is cured by the teachings of Noda et al.

Noda et al. teach an anti-inflammatory and analgesic gel composition comprising a gelling agent selected from methylcellulose and hydroxyethylcellulose. (See column 14, claim 7).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute methylcellulose for hydroxyethylcellulose in the composition taught by Broh-Kahn et al., as suggested by Noda et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Noda et al. teach that these gelling agents are suitable alternatives for one another.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

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ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Claims 2-5, 8, 9 , 10, and 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Broh-Kahn et al. (US Patent 3257276, Published 06/21/1966) in view of Burnier et al. (US Patent 5736574, Published 04/07/1998) further in view of Modak et al. (US Patent 596510, Published 04/07/1998) as evidenced by Page (US Patent 4870108, Published 09/26/1989).

Applicant Claims

Applicant claims a composition comprising alcohol, water, hydroxyethylcellulose, an emollient, octoxyglycerin and an antimicrobial. Further comprising other suitable components such as emulsifiers, thickening agents, and silicone polymers.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Brohn-Kahn et al. and Burnier et al. are discussed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Broh-Kahn et al. lacks a composition comprising emulsifiers, thickening agents, and silicone polymers. This deficiency is cured by the teachings of Modak et al.

Modak et al. teaches a topical composition comprising a gel formed between zinc gluconate and solvent selected from the group consisting of water and alcohol and

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mixtures thereof, and further comprising a thickening agent, a hydrophobic polymer, an emulsifying agent, an emollient, and an antioxidant. The thickening agent is selected from a stearyl alcohol and cationic hydroxyethyl cellulose; the hydrophobic polymer is selected from dimethicone, petroleum and byproducts thereof; the emulsifying agent is selected from PEG-14M and Incroquet Behenzyl TMS. The zinc gluconate is useful as an anti-irritant effect on the skin. The composition can further include antimicrobials. (See abstract, column 26, Lines 14-67 and column 27, Lines 1-14).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add emulsifiers, thickening agents, and silicone polymers the composition taught by Broh-Kahn et al., as suggested by Modak et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Modak et al. teach that such components are common adjuvants added to hydroalcoholic gels.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

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ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616